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**INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference E31806 RLI/J	<b>FOR FURTHER ACTION</b> See Form PCT/IPEA/416	
International application No. PCT/NO2003/000364	International filing date (day/month/year) 31.10.2003	Priority date (day/month/year) 14.11.2002
International Patent Classification (IPC) or national classification and IPC C07C 67/03, C11C 3/02, C11C 3/06, C07C 69/52, C07C 69/587, C12P 7/64		
Applicant Pronova Biocare AS et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a. ☐ (sent to the applicant and to the International Bureau) a total of \_\_\_\_\_ sheets, as follows:
    - ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) \_\_\_\_\_, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- |                                     |              |   |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the report   |
| <input type="checkbox"/>            | Box No. II   | Priority  |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention  |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited   |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application  |
| <input type="checkbox"/>            | Box No. VIII | Certain observations on the international application   |

Date of submission of the demand  14.06.2004	Date of completion of this report  04.03.2005
Name and mailing address of the IPEA/SE Patent- och registreringsverket Box 5055 S-102 42 STOCKHOLM Facsimile No. +46 8 667 72 88	Authorized officer  Eva Johansson/EÖ Telephone No. +46 8 782 25 00

Form PCT/IPEA/409 (cover sheet) (January 2004)

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_ as originally filed/furnished
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (*specify*): \_\_\_\_\_
- ☐ any table(s) related to the sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	<u>1-19</u>	YES
	Claims		NO
Inventive step (IS)	Claims	<u>1-19</u>	YES
	Claims		NO
Industrial applicability (IA)	Claims	<u>1-19</u>	YES
	Claims		NO

## 2. Citations and explanations (Rule 70.7)

The following documents are cited in the International Search Report:

- D1) Journal of the American Oil Chemists' Society, Vol.75, no. 11, 1998, pages 1551-1156.  
D2) Journal of the American Oil Chemists' Society, Vol.74, no. 11, 1997, pages 1425-1429.  
D3) WO 0073254 A1  
D4) Journal of Chromatography A, vol. 704, 1995, pages 211-216.  
D5) DATABASE WPI Derwent AN 1994-260804 & JP 61 92683  
D6) STN International, File CAPLUS AN 1992:406541, DN 117:6541  
D7) Journal of the American Oil Chemists' Society, vol. 74, no. 11, 1997, pages 1419-1424.  
D8) WO 9524459 A1

The invention relates to a lipase catalysed esterification of marine oils.

More specifically, the claimed invention relates to a process for separating an ethyl or methyl ester fraction enriched in EPA and a free fatty acid fraction enriched in DHA. This is obtained from a direct esterification of fish oil free fatty acids with an ethanol or methanol lipase, by molecular distillation.

D1) discloses the use of lipases as catalysts for separating of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in fish oil by kinetic resolution. Transesterification of various fish oil triglycerides with a stoichiometric amount of ethanol by immobilized Rhizomucor miehei lipase (MML) under

.../...

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

anhydrous solvent-free conditions results in a good separation.

D2) discloses a similar process for the preparation of highly purified concentrates of eicosapentaenoic acid (EPA) and docosaheptaenoic acid (DHA). This is obtained by a lipase-catalyzed transesterification including short-path distillation. A lipase-catalyzed transesterification with ethanol is carried out and a mixture of mono-, di-, and triacylglycerols comprising mostly both EPA and DHA is obtained.

The EPA- and DHA-containing acylglycerols can be separated from the saturated and monounsaturated ethyl esters by short path distillation.

D3) discloses a process for producing highly concentrated preparations of polyunsaturated fatty acids and their esters from oil, especially fish oils. The process uses a combination of transesterification of the triglycerides with a lower alcohol, molecular distillation and selective enzymatic transesterification with an alkoxy alcohol catalysed by lipases which desirably can be immobilized. Obtained fatty acids from the process are eicosapentaenoic acid (EPA) and docosaheptaenoic acid (DHA).

The document D1 is regarded as being the closest prior art to the subject-matter of the claims.

The invention according to the claims differs from the method in D1 in that the process includes a distillation part.

Consequently, with the background of D1, the problem is to produce an improved process for separating an ethyl or methyl ester fraction enriched in EPA and a free fatty acid fraction enriched in DHA and this is obtained by the distillation part.

Although, both D2 and D3 contain a short path distillation, the distillation part is not used in the same way as in the claimed invention.

.../...

## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

Thus, a person skilled in the art, having the device known from D1 as a starting point, aiming to solve the identified problem, would not with the knowledge of D2 or D3, thus arrive at the invention according to the claims.

D4-D8 disclose only disclose the general state of the art, and are not considered to be of particular relevance.

Accordingly, the invention defined in claims 1-19 is novel and is considered to involve an inventive step. The invention is industrially applicable.